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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,888	04/14/2004	Julia T. Lathrop	51821-0121 (51821-299534)	7107
47234 7590 06/18/2007 LAW OFFICES OF KHALILIAN SIRA, LLC 9100 PERSIMMON TREE ROAD POTOMAC, MD 20854			EXAMINER COUNTS, GARY W	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 06/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/823,888	Applicant(s) LATHROP ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/23/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> .           |

Continuation of Attachment(s) 6). Other: the claims have been renumbered under rule 1.126.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group III, claims 1-16, 18 and 19 and species SEQ ID NO:3 in the reply filed on March 8, 2007 is acknowledged. The traversal is on the ground(s) that the appropriate treatment in the instance is examination of claims 1-16 in their entirety, with the species of SEQ ID NO: 3 being elected as a species for purposes of initial search and examination. The examiner agrees with the assessment that the restriction is based on a species restriction and therefore Examiner will examine the claims in their entirety with species of SEQ ID NO: 3 as being elected as the species.

Note: it is noted that no claim 16 existed when the application was filed 04/14/04. Therefore the claims have been renumbered in accordance with 37 CFR 1.126 (see below).

### ***Specification***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). The claims filed 04/14/04 did not contain a claim 16. Therefore, the claims have been renumbered 1-18.

Misnumbered claims 1-19 been renumbered 1-18.

***Claim Objections***

3. Claim 1 is objected to because of the following informalities: Claim 1, line 1 the recitation "having binding specificity a protein" should be --having binding specificity for a protein-- . Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a recitation making clear that only the isoform is transferred to and immobilized on a second support. The specification on page 9, lines 6-7 discloses that only the isoform (not the ligand) is transferred to and immobilized on the second support. The claim does not make clear if the protein isoform is still in the form of the complex with the ligand or if the protein isoform has somehow been removed or dissociated from the ligand.

7. Claim 1 steps a, b and c the recitation "under conditions allowing formation" renders the claim unclear, vague and indefinite because said recitation does not clearly define the metes and bounds of the claimed subject matter.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-6, 8, 9, and 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Hammond et al (US 2004/0229280).

Hammond et al disclose a method for identifying a ligand having specificity for a protein isoform (page 13 – page 15). Hammond et al disclose contacting one or more ligands such as trimers (para. 0137 & para. 0153) with a sample that contains different protein isoforms such as PrPc and PrPsc. Hammond et al disclose contacting the complexes formed with antibodies (first detection marker) and detecting a signal (para. 0141 & para. 0153). Hammond et al disclose that the ligands can be on beads and complexes formed on these beads. Hammond et al also disclose that the beads with the complexes can be immobilized in an agarose gel (first support). Hammond et al disclose that the protein isoforms can be transferred from the first support to a capture membrane (second support)(Fig. 5 & para. 0153). Hammond et al disclose contacting the transferred isoforms with antibodies (second detection marker) and detecting a signal. Hammond et al disclose alignment of the spots from the signals and determining the ligands have specificity for the protein isoforms (para. 0145, 0153). Hammond et al

Art Unit: 1641

disclose that the protein isoform can be modified by digestion or modified by denaturation. Hammond et al disclose that the ligand can be SEQ ID NO 114 (which has a 100% match with SEQ ID NO: 3 of the current application).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1641

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al (US 2004/0229280) in view of Drobnik et al (US 4,245,064) or Hammond et al (US 7,217,507).

See above for the teachings of Hammond et al (US 2004/0229280)

Hammond et al (US 2004/0229280) differs from the instant invention in failing to teach the ligand is immobilized directly on the first support.

Drobnik et al teaches that it is known in the art to immobilized ligands to a carrier support and that bonding of the ligand to the support may occur immediately (directly) to the carrier or by means of a linker (indirectly) (col 1, lines 7-42).

Hammond et al (US 7,217,507) teaches that it is known in the art to directly or indirectly attach ligands to a support (col 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate direct attachment of the ligand to the support as taught by Drobnik et al or Hammond et al (7,217,507) into the method of Hammond et al (2004/0229280) because both Drobnik et al and Hammond et al teach the equivalence of direct and indirect attachment of ligands to a support and the selection of any of these known equivalents to attach the ligand of Hammond et al (2004/0229280) reference would be within the level of ordinary skill in the art.

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al (US 2004/0229280) in view of Charlton et al (US 5,989,921).

See above for the teachings of Hammond et al (US 2004/0229280).



Hammond et al differs from the instant invention in failing to teach the ligands are immobilized on the first support prior to contacting with the one or more ligands.

Charlton et al disclose beads having immobilized binding partners used in binding assays. Charlton et al disclose that these beads are entrapped or linked to sorbent material (support) prior to contact with a sample (col 3, lines 39-45 and col 6, lines 16-30). Charlton et al disclose that this provides for improved sensitivity in assays (col 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize the beads of Hammond et al to the support prior to sample contact such as taught by Charlton et al because Charlton et al teaches that this provides for binding assays with improved sensitivity.

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al (US 2004/0229280) in view of Wang (US 2002/0155493).

See above for the teachings of Hammond et al (US 2004/0229280).

Hammond et al (US 2004/0229280) differs from the instant invention in failing to teach the ligands form an array on the first support.

Wang teaches ligands which are immobilized in pre-defined positions on a support to form an array (paragraphs 0003 and 0004). Wang teaches that this provides for the later identification of the ligand. Wang also teaches that this provides for biological research, clinical diagnostics and drug development and the study of protein-protein interactions (paragraphs 0003 and 0004).

Art Unit: 1641

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate arrays as taught by Wang into the method of Hammond et al because Wang teaches that this provides for the later identification of the ligand and also teaches that this provides for biological research, clinical diagnostics and drug development and the study of protein-protein interactions.

### ***Conclusion***

16. No claims are allowed.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

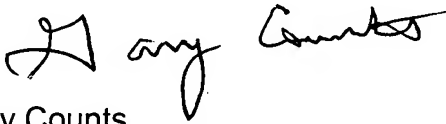
Cashman et al (US 2006/0183156) teaches PRPSC-selective peptides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gary Counts  
Examiner  
Art unit 1641  
June 6, 2007



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